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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,745	04/09/2004	Michael Snyder	1030.004	1863

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,745	SNYDER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for pre-appeal brief request filed 01/06/2009.

In view of the pre-appeal brief request filed 01/06/2009, the prosecution is hereby reopened. New grounds of rejections set forth below.

Claims 11 and 21-24 are pending and included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "the wound" in second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 further recites the limitation "mass" in third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Additionally, claim 22 recites the expression "other mass" that does not set forth the metes and bounds of the claim. Recourse to the specification does not define "mass" or "other mass".

Regarding claim 24, the claim recites the limitation "the layer" in second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,360,399 ('399) combined with US 7,354,574 ('574).

Present claim 11 is directed to implant having lumen and having openings in the wall and in its lumen comprises composition comprising caprolactone and antimicrobial agent. The lumen is circular and the sustained release material is solid.

US '399 teaches glaucoma drainage tube that is made of plastic and contains orifices of fixed sizes and shapes (abstract; col.2, lines 4-9; col.3, lines 45-57; col.4, lines 65-67). Figure 4 shows that lumen is circular and has fixed inner and outer dimensions. The tube has lumen containing composition comprising active agent to be deliver and escape through the orifices contained in a viscous solution of hyaluronic acid and its derivatives (col.4, lines 20-25; col.5, lines 21-40).

Although US '399 teaches delivery of active agent in viscous medium, however, the reference does not teach the active agent delivered from sustained release medium that comprises caprolactone and antimicrobial agent as instantly claimed by claim 11.

US '574 teaches implantable composition for treating ocular diseases (abstract). The composition comprises antimicrobial agent (cyclosporine) in polymer matrix of polycaprolactone contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the drug over the time (col.2, lines 9-15; col.3, lines 18-25, 42-48, 56-65). Cyclosporine, beside being antimicrobial drug, it slows progress of some ocular diseases and lessens their severity because it has immunosuppressive activity (col.4, lines 23-30; col.5, lines 11-13).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implant comprising glaucoma drainage plastic tube having orifices and contain medium to deliver active agent to the surrounding tissue as disclosed by US '399, and replace the medium containing the active agent with the formulation comprising polymer matrix of polycaprolactone and cyclosporine that is formulated to release non-toxic therapeutic amount of the cyclosporine as disclosed by US '574. One would have been motivated to do so because US '574 teaches that composition comprises cyclosporine in polycaprolactone matrix provides sustained release composition and releases non-toxic therapeutic amount of the cyclosporine over the time and because cyclosporine beside being antimicrobial drug, it slows progress of some ocular diseases and lessens their severity because it has immunosuppressive activity. One would reasonably expected formulating plastic glaucoma drainage tube containing orifices and circular lumen containing polycaprolactone matrix comprising cyclosporine wherein the matrix provides sustained release of non-toxic doses of cyclosporine to provide antimicrobial effect as well as immunosuppressive effect to slow progress of some ocular diseases and lessen their severity.

Regarding the limitation of increase of the degree of opening of the head space passage as claimed by claim 11, the combined teaching of US '399 and US '574 provides glaucoma drainage tube having lumen filled with polymer composition comprising bioerodible caprolactone, and it is expected that caprolactone will be eroded forming the head space passage that increase by time, since material and properties are inseparable.

6. Claim 22 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '399 and US '574 and further in view of US 4,743,255 ('255).

The combined teaching of US '399 and US '574 are previously discussed as set forth in this office action.

However, the references do not teach radiologically detectable marker material as claimed by claim 22.

US '255 teaches intraocular implantable material that can be incorporated with radio-opaque marker material for follow up using simple radiological technique without resorting to complex imaging techniques (col.1, line 64-col.2, line 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implant comprising glaucoma drainage plastic tube having orifices containing sustained release polycaprolactone formulation comprising cyclosporine as disclosed by the combined teachings of US '399 and US '574, and further add radio-opaque material that can be detected by radiology to the implant as disclosed by US '255. One would have been motivated to do so because US '255 teaches that radio-opaque marker material helps follow up using simple radiological technique without resorting to complex imaging techniques. One would have reasonably expected formulating implant comprising glaucoma drainage plastic tube containing sustained release polycaprolactone formulation comprising cyclosporine and radio-opaque marker material that helps follow up by simple radiology technique.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '399 and US '574 and further in view of US 6,692,759 ('759).

The combined teaching of US '399 and US '574 are previously discussed as set forth in this office action.

However, the references do not teach layered sustained release material as claimed by claim 23.

US '759 teaches ocular implantable devices for sustained release of active substances including antimicrobial agents to tissues adjacent to the area of implantation (abstract; col.3, lines 32-38; col.5, lines 17-20; col.8, lines 45-64). The implant is multi-layered to deliver two or more active agents to reach different surrounding regions and particularly useful for delivering two or more active substances (col.6, lines 58-63; col.9, lines 26-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implant comprising glaucoma drainage plastic tube having orifices containing sustained release polycaprolactone matrix comprising antimicrobial agent as disclosed by the combined teachings of US '399 and US '574, and further formulate the matrix into multilayered matrix as disclosed by US '759. One would have been motivated to do so because US '759 teaches that multi-layered implantable delivery device is particularly useful for delivering one or more active substances to the surrounding regions. One would have reasonably expected formulating implant comprising glaucoma drainage plastic tube containing multi-layered

sustained release polycaprolactone matrix comprising more than one active agent to provide more than one beneficial agent to the surrounding regions to patient in need.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '399 and US '574 and further in view of US 5,512,055 ('055).

The combined teaching of US '399 and US '574 are previously discussed as set forth in this office action.

However, the references do not teach coated implant as claimed by claim 24.

US '055 teaches coated implant comprising polymer and anti-infective agent to decrease the infection in the tissue surrounding the implant by sustained release of the anti-infective agent (col.5, lines 25-34).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implant comprising glaucoma drainage plastic tube having orifices containing sustained release polycaprolactone formulation comprising antimicrobial agent as disclosed by the combined teachings of US '399 and US '574, and further coat the composition onto the implant as disclosed by US '055. One would have been motivated to do so because US '055 teaches that polymer coating of implant comprising anti-infective agent will decrease the infection in the tissue surrounding the implant by sustained release of the anti-infective agent. One would have reasonably expected formulating implant comprising glaucoma drainage plastic tube coated with sustained release polycaprolactone formulation comprising anti-infective agent to decrease the infection in the tissue surrounding the implant.

Response to Arguments

9. Applicant's arguments filed 01/06/2009 have been fully considered but they are not persuasive.

Applicants argue that US '399 teaches hydraulic expansion and traumatic opening of the upstream tissue of the Schlemm's canal and does not teach having the device itself pierce the upstream tissue of the Schlemm's canal, therefore, the apparatus itself does not facilitate reduction of intraocular pressure by allowing the fluids to flow through the glaucoma shunt to a different area of the eye. The reference teaches that the tubes are removed once the opening of the upstream tissue has been completed.

In response to this argument, applicants' attention is directed to the scope of the present claims that is drawn to product, and all the elements of the product is taught by the combined teaching of US '399 and US '574 as instantly presented. The present claims are directed to implant having lumen and having openings in the wall and in its lumen comprises composition comprising polycaprolactone and antimicrobial agent, and the combination of the references teach all the limitations required by the claims. Applicants' argument is directed to the intended use of the tube and its duration of use. It is further argued that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the

instant case, US '399 is capable to perform the same function required by applicants which is maintaining the intraocular pressure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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